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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,166	07/23/2003	Gregory Everett Amidon	PC28053	9717
23913	7590	09/14/2006	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/626,166	Applicant(s) AMIDON ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/12/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-3, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claims 1-3 and 23 recite the use of a starch with a specific tensile strength; the claims are indefinite because more information is needed on how the tensile strength is measured. From the specification it discloses the tensile strength was measured as a fraction of the overall tablet, which was compressed, nowhere in the claims does it disclose the test conditions. The claims currently read on just the tensile strength of a starch without disclosing its physical form (free powder or compressed with other ingredients) or how the tensile strength was measured and is therefore indefinite. To expedite the examining process the examiner will search for a tablet containing the ingredients in claim 1 with the disclosed tensile strength. Regarding claim 22 it is not clear what is encompassed by nonfunctional coating, while defined in the specification adequately the claim is indefinite because what nonfunctional comprises is not adequately defined within the claim. To expedite the examining process the examiner will search for a coating comprising additional ingredients.

Claim 23 contains the trademark/trade name HPMC type 2208. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App.

1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific HPMC and, accordingly, the identification/description is indefinite. To expedite the examining process the examiner will search for HPMC in claim 23 and ignore the type 2208 claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,8-9,13-20 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Holman (US 6,277,875 B1, cited by applicants).

Holman discloses dopamine D2/D3 receptor antagonist for treatment of Fibromyalgia, the treatment can comprise administering pramipexole dihydrochloride monohydrate in the form of MIRAPEX® which is disclosed as containing HPMC and pregelatinized starch, the amount of pramipexole is within applicants claimed ranges. See abstract, col 8 lin 49-57 and col 11 lin 30-46. Regarding the limitation on the tensile

strength of starch, the only limitation used in the body of the claims on the type of starch that would meet the limitation of the tensile strength is a pregelatinized starch therefore Homan meets this limitation because the same compound will have the same properties such as tensile strength when compressed under the same amount of force to form a tablet form. Regarding claims 19-20, Holman teaches that if the composition is in the form of a tablet or capsule it may be coated in a sugar or enteric coating as known in the art. Regarding claim 25 Holman teaches the amount of pramipexole in a MIRAPEX® tablet is 0.125-1.5 mg, and claims a therapeutic amount as low as 0.25 mg per day, therefore it is inherent that one tablet could be used to deliver the therapeutic amount needed in one day. Regarding claim 26 while the Homan patent discloses treating Fibromyalgia with pramipexole the patent also teaches that pramipexole can be used for the treatment of Parkinson's disease therefore the limitation is met. See col 2 lin 48-67.

Claims 1-4,8-4,19-20,22,24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (US 2003/0180352).

Patel discloses solid carriers for improved delivery of active ingredients in pharmaceutical compositions, the active ingredients included anti-Parkinson's drugs such as pramipexole and its salts and the pharmaceutical composition could comprise a solubilizer such as HPMC (within applicants claimed weight range) and binders such as pregelatinized starch, all of the above can be in the form of a tablet. See abstract, [0052],[0061],[0226]-[0227],[0241],[0272], [0365]. Regarding the limitation on the tensile strength of starch, the only limitation used in the body of the claims on the type of starch

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that would meet the limitation of the tensile strength is a pregelatinized starch therefore Patel meets this limitation because the same compound will have the same properties such as tensile strength when compressed under the same amount of force to form a tablet form. Regarding claims 19-20 and 22 Patel discloses that the pharmaceutical composition can be coated with HPMC and ethyl cellulose, also the coating can include an inert-processing aid. See [0273]-[0280].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1, cited by applicants).

Holman is disclosed above. While Holman discloses using inactive ingredients such as HPMC and pregelatinized starch in MIRAPEX® tablets the patent does not disclose the exact amounts of those inactive ingredients. It is the position of the examiner however that one skilled in the art would through routine experimentation would find the optimum amount of fillers, binders and other ingredients to produce a tablet with the desired characteristics such as tablet hardness and release profile. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2003/0180352).

Patel is disclosed above. While Patel discloses tablets comprised of pramipexole, HPMC and pregelatinized starch the patent does not disclose the amount in weight % compared to the overall weight of the tablet of pregelatinized starch and the coating, the amount of pramipexole and the ratio of ethylcellulose or water-insoluble component and HPMC used in the coating. It is the position of the examiner however

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that one skilled in the art would through routine experimentation find the optimum amount of fillers, binders, coatings, ratio of ingredients in the coating and other ingredients to produce a tablet with the desired characteristics such as hardness and release profile. Besides the arguments from above, In re Aller and In re Hoeschele from the rejection above apply as well.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1, cited by applicants) in view of Khan et al. (US 5,656,296, cited by applicant) in view of Petrus et al. (WO 00/59477 A1, cited by applicants) in further view of Michaud et al. (EP 0,933,079 A1, cited by applicants).

Holman is disclosed above. While Holman discloses using inactive ingredients such as HPMC, and pregelatinized starch as well as coating the tablets, the patent does not disclose the exact amounts of those inactive ingredients nor does the patent disclose the use a coating comprising a water-insoluble component and HPMC within the ratio specified by applicant.

Khan is used to primarily show that a coating comprised of a water-insoluble component and HPMC-based pore forming component within the ratio to each other and weight percent of the overall tablet as claimed by applicant was well known at the time of the invention. The coating was already known to be useful for sustained release drug delivery systems. See abstract and col 6 lin 34-col 7 lin 17. Also disclosed in Khan is that the coating can contain conventional excipients and additives which function to facilitate processing or storage.

Petrus is used to show that the amount of HPMC and pregelatinized starch within the weight percent of the overall tablet specified by applicant was well known in the art at the time of the invention for use in controlled release formulations for Parkinson's disease. See abstract and pag 20 lin 21-37.

Michaud is used only to show that pregelatinized starch was already known to have tensile strength within applicants claimed amounts when compressed into a tablet form. See tables 3,6,9-13.

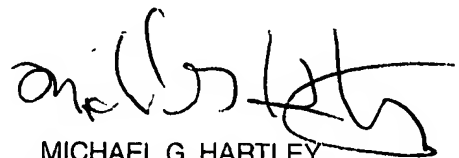
It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Holman discloses all of applicants claimed invention except for the exact amount of HPMC, pregelatinized starch and coating used, the tensile strength of the pregelatinized starch and Holman was silent on the exact coating used while Khan, Petrus and Michaud showed the amounts of HPMC, pregelatinized starch and coating as well as the exact coating and tensile strength of pregelatinized starch were all well known in the art to be used in controlled release pharmaceutical formulations. The motivation to combine the above documents would be a controlled release tablet comprised of pramipexole dihydrochloride, HPMC and pregelatinized starch all contained in a coating comprising a water-insoluble component and an HPMC-based pore-forming component. The advantage of such a tablet for the treatment of Parkinson's would be a tablet having a sufficient hardness to resist erosion. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER